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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,061	12/30/2003	Geoffrey H. Willis	GUID-034	7376

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EXAMINER

KILKENNY, PATRICK L

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/749,061		WILLIS, GEOFFREY H.	
	Examiner		Art Unit	
	Patrick J. Kilkenney		3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-19, 23, 25-30 and 33-43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-4, 6-11, 15-19, 23, 25-30, 33 and 34-43 is/are rejected.
 7) ☒ Claim(s) 12-14 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/02/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6-11, 15-19, 25-30, 35, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckman Jr. et al. (5,484,391). Buckman Jr. et al. discloses a device capable of manipulating and positioning a heart, absent clinically relevant hemodynamic instability, with an inflatable annular member (Fig. 6, #82) with a central opening (Fig. 7, space through which 76 passes into 82), and an organ-contacting surface (Fig. 6, #86). The annular member can be inflated with liquid or gas (Column 9, lines 41-42). The heart-contacting surface is made of a cushioning compliant material (Claim 4), specifically a foam rubber (Column 6, lines 64-67). This contacting material is configured to conform to and diffuse suction exerted on the organ (Column 6, lines 55-59). There is also vacuum source to supply negative pressure to the surface of the organ coupled to the positioning element and a vacuum distribution element associated with the annular member configured to diffuse suction exerted on the heart (Fig. 7, #80; Fig. 8, #120; Column 11, lines 17-22). The vacuum distribution element (Fig. 8, #120) is made of a foam rubber since it is an indentation of the end of the contacting member, (Fig. 8, #112), which is analogous to heart contacting member (Fig. 1, #16 and Column 11, lines 4-6). There is also a vacuum distribution source at

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the terminal end of the lumen, between it and the opening, that regulates and distributes positive and negative pressures (88 and 90). There is a position element (Fig. 6, #76), comprising a lumen, coupled to a vacuum source via an independent fluid pathway (Fig. 7 #'s 80 and 90; Column 9, lines 43-45) and to the inflatable member where it closes off the opening and a regulator for controlling the vacuum flow (Fig. 7, #92; Columns 9-10, lines 67-3). The inflatable annular member is fluidly sealed and coupled to the positioning element with a series of attachment means (Fig. 7, #'s 84A and 104), which are made of plastic as disclosed for all embodiments of the heart contacting members (Column 6, lines 51-53), and silicone material. Limited movement is possible at this joint. Also disclosed is a spring element system (Figs. 9-11, #'s 144 and 156 specifically) associated with the positioning element that allows axial movement of the inflatable annular member (Column 11, lines 36-38). There is also a sheath of inner and outer sleeves (Fig. 10, #'s 146 and 156) that can retain the deflated device for insertion into the body cavity Fig. 11, # 146). There is also a second lumen connected to the inflatable member that carries a light source (174) that passes through, but is not fluidly connected to the opening in the inflatable member.

Buckman Jr. et al. also discloses methods for manipulating and positioning the heart, possibly during the absence of clinically relevant hemodynamic instability, with the device described above by introducing the device into the body cavity via a thoracotomy (Column 15, lines 12-14 and 34-48). The device is capable of being inflated with gas or liquid to its expanded state once out of the sheath (Column 9, lines 41-42), and a vacuum source can then be operatively coupled to the positioning

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element to create a negative pressure for suction on the heart while maintaining the inflated state that can attach to the heart. The negative pressure applied can also cause deflation of the annular member prior to attachment when it is not in contact with the heart and allow for the device to be inserted into the sheath (Column 10, lines 27-33, 50-53, and 58-61). Again, a sheath is disclosed for inserting the device in the body cavity (Fig. 11, #146) and the vacuum exerted on the organ is diffused by a vacuum distribution element and the surface conforms to the heart surface (Fig. 8, #120).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Heaven et al. (5,337,754). Buckman Jr. et al. discloses the claimed invention with the exception of the seams of the inflatable annular member being positioned on the interior of the member. Heaven et al. discloses an medical retractor with an inflatable member that utilizes internal seams yielding less traumatic surfaces on the exterior (Column 6, lines 3-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Buckman Jr et al. with internal seams, as taught by Heaven et al., which would result in a less traumatic surface being applied to the heart.

Claims 23 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Peng et al. (6,506,149). Buckman Jr. et al. discloses the claimed invention except for a securing means and a method for securing the device to a stationary object. Peng et al. discloses a heart manipulator capable of, and a method for, securing the device to a stationary retractor (Fig. 1, 4A and Column 10, lines 24-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manipulator device of Buckman Jr. et al. with a means and method for securing the manipulator device to a stationary object, as taught by Peng et al., since it is ideal to have retractor systems secured during any type of medically related operational procedure.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Taylor et al. (5,906,607). Buckman Jr. et al. discloses the claimed method with the exception of performing a coronary artery bypass on the organ. Taylor et al. discloses a coronary artery bypass procedure on a heart being stabilized with a vacuum source retractor (Fig. 4). Furthermore, Taylor et al. discloses in the background and summary of their invention the benefits of using vacuum retractors for performing surgeries involving block coronary vessels. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Buckman Jr. et al. with a coronary bypass procedure, as taught by Taylor et al., because coronary bypass procedures are among the most common heart surgeries that require manipulation of the heart, ideally while still beating.

Claims 36-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. Buckman Jr. et al. discloses the claimed invention, as described above, with the exception of kit with a plurality of devices and instructions for using the device. The examiner takes Official Notice that it is obvious to provide instructions within a device kit to enable correct utilization of the device. Therefore, it would have been obvious to provide instructions in a kit along with the device of Buckman Jr. et al., and it would have been obvious to provide a plurality of organ manipulation devices (subcombinations) in the kit (device/combination) since it has been held that mere duplication of the essential working parts of a device (i.e. the kit) involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al., as applied to claim 35 above, and further in view of Peng et al. Buckman Jr et al. discloses the claimed invention with the exception of a securing means for securing the device to a stationary object. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manipulator device of Buckman Jr. et al. with a securing means, as taught by Peng et al., so that the organ manipulator device can effectively hold the retracted organ in desired position without the aid of a person during an operational procedure.

Allowable Subject Matter

Claims 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 2/6/2006 have been fully considered but they are not persuasive with respect to the following claims. With respect to independent claim 1, the examiner is applying the following definition of the word "through:" among or between. With respect to claim 25, the device is capable of being inflated with gas or liquid to its expanded state once out of the sheath (Column 9, lines 41-42), and a vacuum source can then be operatively coupled to the positioning element to create a negative pressure for suction on the heart while maintaining the inflated state that can attach to the heart. The negative pressure applied can also cause deflation of the annular member prior to attachment when it is not in contact with the heart and allow for the device to be inserted into the sheath (Column 10, lines 27-33, 50-53, and 58-61). With respect to the argument that cushioning compliant material of the of Figs. 1-3 not being attached to a vacuum source the material and nature of the material is generally disclosed but applies to all embodiments of the device of Buckman Jr. et al. Hence, the material and function of the suction cup of Figs. 6-8 are functionally equivalent. With respect to the arguments of claim 9, the silicone seal of the attachment between the

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lumen and the inflatable cup must be fluidly sealed for Buckman Jr. et al. to function and limited freedom of movement, as broadly claimed, is inherent in the attachment joint.

In response to Applicant's argument that the device of Buckman Jr. et al. is used for cardiac compression and also, not used for coronary bypass surgery, the fact that Applicant uses the inflatable retractor for a different purpose does not alter the conclusion that its use in a prior art device would be prima facie obvious from the purpose disclosed in the reference. It is capable of being used solely as a retraction device, possibly during coronary artery bypass surgery, which would not alter the hemodynamics of the heart.

Applicant's arguments filed 2/6/2006, with respect to claims 12-14 have been fully considered and are persuasive. The rejection of claims 12-14 has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick J. Kilkenny whose telephone number is (571) 272-8684. The examiner can normally be reached on Mon-Fri, 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PJK


Patrick J. Kilkenny
Art Unit 3732
May 1, 2006
5/1/06


PATRICIA BIANCO
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5/1/06